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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/120,044 07/21/98 MINETTI

C 1758-4036US2

EXAMINER

HM12/0804

DEVIS

ART-UNIT**PAPER NUMBER**

1641

10**DATE MAILED:**

08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|-------------------------------|--------------------------------|
| Application No. 09/120,044 | Applicant(s) Minetti et al. |
| Examiner S. Devi, Ph.D. | Group Art Unit 1641 |

Responsive to communication(s) filed on Mar 8, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-30 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

- 1) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 2) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15 and 22-26, drawn to a modified pneumolysin polypeptide, a vaccine and a conjugate comprising the same, classified in class 530, subclass 825.
 - II. Claims 16-21, drawn to a recombinant nucleic acid molecule and a microorganism comprising the nucleic acid, classified in class 536, subclass 23.7.
 - III. Claims 27 and 28, drawn to a method of killing bacteria using antibodies directed to the modified pneumolysin in the presence of a complement, classified in class 435, subclass 7.2 and 32.
 - IV. Claim 29, drawn to a method for immunization of mammals using the vaccine, classified in class 424, subclasses 190.1 and 244.1.
 - V. Claim 30, drawn to a method for obtaining modified pneumolysin polypeptides by expressing the mutated nucleic acid molecule in host cells, class 435, subclass 252.3.
- 4) Inventions I, II, III, IV and V are patentably distinct from one another. Inventions I and II are directed to two distinct products. Invention I is drawn to a polypeptide and Invention II to a nucleic acid molecule and a microorganism comprising the nucleic acid. The two products clearly differ from each other structurally and functionally, and they also exert distinct biologic effects.
- 5) Inventions I, and inventions III and IV are related as product and process(es) of use. The

inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the method of killing bacteria of invention III can be practiced with another product that is materially different from the product of invention I, for example, an antibiotic. The method of immunization of mammals of invention IV can be practiced with another product that is materially different from the modified pneumolysin of invention I, for example, a non-pneumolysin antigen such as a pneumococcal polysaccharide.

6) Inventions I and V are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the composition of invention I can be made by a materially different process, for example, a chemical synthetic process, without involving the expression of the recited mutated nucleic acid molecule in a host cell.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

7) The instant application contains claims directed to patentably distinct species of the claimed invention. Election to one of the following species of modified pneumolysin polypeptides, which are distinct in their amino acid sequences, is required: pNVJ1 of claim 7; pNVJ20 of claim 8; pNVJ22 of claim 9; pNVJ45 of claim 10; pNVJ56 of claim 11; pNV103 of claim 12; pNV207 of claim 13; pNV111 of claim 14, and pNV211 of claim 15. Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

9) Should Applicants traverse on the ground that the species are not patentably distinct,

Serial Number 09/120,044

Art Unit: 1641

Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

11) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 1999


JAMES C. HOUSEL 8/3/99
SUPERVISORY PATENT EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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